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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,601	08/24/2006	Sabine Balthasar	RO4304US (#90568)	8967

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EXAMINER	
WHEELER, THURMAN MICHAEL	
ART UNIT	PAPER NUMBER
1619	
MAIL DATE	DELIVERY MODE
06/02/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/590,601	BALTHASAR ET AL.	
	Examiner	Art Unit	
	Thurman Wheeler	1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 February 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-14 and 16-18* is/are pending in the application.

4a) Of the above claim(s) *6-14,17 and 18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,5 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1, 2, 4-14, 16-18 are pending in instant application

1. Any rejection or objection not reiterated in this Action is withdrawn.

2. Claims 1, 4 and 16 have been amended. Claims 3 and 15 have been cancelled. Claims 6-14, 17 and 18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected claims, there being no allowable generic or linking claim.

Herein, claims 1, 2, 4, 5 and 16 are for further prosecution.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 5 and 16 are rejected under 35 U.S.C. 102(b) as anticipated by Kreuter et al (WO 02089776) where USP 2004/0131692 is used as English equivalent of PCT/EP2002/004735. Citations are to the English equivalent document.

Kreuter teaches nanoparticles comprising proteins, e.g. gelatine ([0009]; [0024], claim 2; claim 13; claim 23) and human serum albumin ([0001]; [0007-8]; [0023]; [0035]; claim 2; claim 13; claim 23) coupled with antibodies ([0012]; claim 5).

Further, Kreuter teaches to impart pharmacologic effects, pharmacologically or biologically active substances are incorporated in the nanoparticles, or they are bound by the nanoparticles, where the binding of the active agents may be performed covalently, with complex-formation via the avidin-biotin system, as well as incorporatively or adsorptively ([0014]; claim 8; claim 9, claim 10).

Kreuter teaches amino groups, carboxyl groups, and hydroxyl groups located on the surface of the nanoparticles can be converted by suitable reagents to reactive thiol groups, where functional proteins are bound to the thiol group-modified nanoparticles via bifunctional spacer molecules having reactivity both to amino groups and free thiol groups [0011]. The functional proteins to be coupled to the nanoparticles are

selected from the group comprising avidin, avidin derivatives, apolipoproteins such as apolipoprotein E, and also antibodies *[0012]*.

The nanoparticles as taught by Kreuter meet the structural limitations of the claims. The nanoparticles comprising gelatine or human serum albumin coupled with antibodies and a pharmacological agent as taught by Kreuter and the nanoparticles as claimed by Applicants are not structurally distinguishable, therefore in the absence of evidence to the contrary the nanoparticles of Kreuter would inherently provide cell-specific, intracellular enrichment of at least one pharmaceutically active substance. A composition and its properties are inseparable.

Toro Co. v. Deere & Co., 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004)("[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention.").

Therefore, claims 1, 2, 4, 5 and 16 are anticipated from the teachings of Kreuter.

Conclusions

4. Claims 1, 2, 4, 5 and 16 are rejected.

Applicants' Arguments

5. Applicants argue that the teachings of Kreuter differ from the presently claimed invention in that Kreuter discloses protein-based nanoparticles possessing apolipoprotein E for crossing the blood-brain barrier, rather than specific antibodies for a cell-specific enrichment. Applicants submit that even if Kreuter generically teaches that various functional proteins such as antibodies may be coupled to the nanoparticles comprising ApoE, Kreuter does not disclose that antibody-labeled protein nanoparticles may be used for intracellular targeting of pharmaceutically active substances adsorbed to, incorporated into or bound to the nanoparticles.

Further, Applicants argue Kreuter teaches specific nanoparticles for a specific task, namely, targeting nanoparticles to the central nervous system, and lack any indication that the particles disclosed therein might be modified in that ApoE is replaced with an antibody.

Applicants' arguments filed 19 Feb 2010 have been fully considered but they are not persuasive.

Kreuter teaches gelatine A, gelatine B, and human serum albumin used to form nanoparticles. Moreover, Kreuter teaches functional proteins, e.g. antibodies, which are coupled to the nanoparticles.

Applicants are directed to Fig. 1, which shows a nanoparticle with a thiol modified surface, spacer group with biotinylated apolipoprotein coupled via avidin. Since Kreuter teaches that the functional protein bound to the nanoparticle can not only be apolipoprotein, but also an antibody (see claim 5), the nanoparticle carrier system as depicted in Fig 1 could also have a biotinylated antibody bound to the nanoparticles. Also, Kreuter teaches that an antibody can be linked via a spacer group coupled to the thiol modified nanoparticle.

Kreuter teaches a composition meeting the structural limitations of the claims. Accordingly, a nanoparticle comprising a pharmaceutical agent and an antibody, as explicitly taught by Kreuter, would also be expected to provide a carrier system for cell-specific, intracellular enrichment of a pharmaceutical agent especially in the absence of evidence to the contrary. Moreover, the Kreuter reference teaches that the functional proteins, e.g. antibodies, themselves can impart pharmacologic effects.

Finally, Kreuter teaches the binding of the pharmacologically or biologically active agents may be performed covalently, with complex-formation via the avidin-biotin system, as well as incorporatively or adsorptively.

1. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

2. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

1. Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thurman Wheeler whose telephone number is (571)270-1307. The examiner can normally be reached on 9:00 a.m.-5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Tracy Vivlemore/
Primary Examiner, Art Unit 1635